3/5/99

K983164 p1of6

510(K) Summary
NEBL Restore Female Incontinence Device

1. Name: NEBL, Inc.
   Address: 44 Terrace Drive
   Worcester, MA 01609
   Phone: 781-322-4501
   Contact: Jeffrey Dann M.D.
   Date Prepared: September 1, 1998

2. Device Name:

   Proprietary Name: Restore (a.k.a. Re/Stor)
   Common Name: Female Incontinence Device
   Classification Name: Device, urethral occlusion for incontinence
   Classification Code: 78MNG

3. Predicate Devices: Impress Soft Patch (Uromed Inc) K974600
   Restore (NEBL Inc.) K971359

4. Device Description

Restore Female Continence device is a simple, noninvasive suction cup which fits over the urinary meatus. Air is squeezed out of the device's cap while it is positioned over the urinary meatus. When the cap is released, the device self-adheres to the anterior vaginal wall over the meatus via suction. If inadequate suction occurs, Aquaphor or a petroleum based ointment can be applied to the outside rim of the device to enhance suction. The suction or negative pressure created by the device causes coaptation and occlusion of the meatus and, therefore, increased urethral resistance. The amount of negative pressure generated by the device is optimized to counteract increases in intra-abdominal and intravesical pressure during valsalva, thereby decreasing or preventing leakage.

5. Intended Use

The Restore device is indicated for the prevention or decrease of episodes of urine leakage in women with stress incontinence.

6. Indications for Use

The Restore device is indicated for the prevention or decrease of episodes of urine leakage in women with stress incontinence.

7. Substantial Equivalence Comparison

The Restore device is substantially equivalent in function, features and indications to the Impress Soft Patch (UroMed, Inc.). Both devices have the same Indications For Use to prevent or decrease episodes of urine leakage in women with stress urinary incontinence. Both devices are worn intralabially over the meatus and occlude the urethral meatus by creating a seal over the urethral opening. Both are applied by patients to the same anatomical position with ease by utilizing similar techniques of device placement. Both are removed to urinate and reapplied after urination is completed.

Restore has several important advantages compared to Impress Soft Patch. First, it does not require a medical adhesive to function; therefore, it should be easier to manipulate into the correct anatomical position or to reapply if initially incorrectly positioned. Secondly, it naturally migrates to the midline of the anterior vaginal wall and, therefore, over the meatus even if slightly malpositioned. Third, there is no risk of mucosal contact or irritation from an adhesive. Fourth, there are fewer restrictions in use such as showering, bathing and swimming since Restore is not composed of hydrophilic material. In summary, Restore appears easier to place, less wasteful and cumbersome to reposition and reapply if inadequately placed, and requires fewer restrictions in use compared to the Impress Soft Patch. Restore also provides protection if inappropriately used by a patient with urgency incontinence secondary to uninhibited bladder contractions since the device easily "pops-off" under this clinical condition.

8. Nonclinical Tests

Restore and its component material has been tested for biocompatibility, Cytotoxicity, Delayed Contact Sensitization, Vaginal Irritation Study, Bacteriostatic Fungistasis, 90 Day Muscle Implantation Study, Microbial Limits Screening, Microbial Limits Prepatory Testing, Bioburden Recovery and Zone of Inhibition Testing. The results indicate the materials and product are biocompatible, nontoxic and well tolerated by tissues.

9. Summary of Clinical Testing

The Restore device has been extensively tested for its safety and efficacy in decreasing or preventing incontinence episodes in women (see K971359). All testing results indicate that the Restore device provides minimal risk yet provides significant benefit for women in controlling urinary leakage.

A. Effectiveness

Clinical testing was completed on 100 women from 8 Investigational Sites in the U.S. Women used the Restore device during a device usage period of 12 weeks to test the efficacy hypothesis that the Restore Continence device will: 1) decrease or prevent incontinence episodes and 2) reduce the impact of incontinence on quality of life. Objective testing included Pad Weight Test (PdWt) and Provocative Stress Test (PST). Subjective testing included a voiding diary documenting the number of incontinence episodes per day (IEPD), an incontinence impact questionnaire and a Satisfaction Survey. Efficacy parameters were statistically analyzed using paired t-test analysis, repeated-measures analysis and Wilcoxon signed rank testing. Analysis demonstrates a statistically significant improvement in all objective and subjective efficacy measures. The Table below details the average measurements before device use (Control) and at the Week 12 Device Utilization Visit.

Test	Control	Week 12	%Improvement	P
PdWt	6.67gm	.19gm	97%	.0001
PST	2	0	100%	.0001
IEPD	3.4	.3	91%	.0001
I-QOL	62.3	90.4	45%	.0001

Breakdown by Visits demonstrated that the effect was immediate with continued improvement as patients became more proficient with device placement.

The women in the Study were stratified into categories of mild (0-2gm), moderate (2-8gm) and severe (greater than 8gm) urinary incontinence based on Baseline PdWt. Analysis of PdWt results demonstrate a statistically significant improvement in urine loss for each subpopulation of subjects.

The impact of urinary incontinence on quality of life is a measure of the patient's perception of the degree to which leakage has a negative effect on various aspects of daily living. A 22 question incontinence impact questionnaire (I-QOL) with a maximum score of 110 evaluated subjects before and during device usage. Subjects demonstrated a significant improvement in their quality of life during device use.

Patient Satisfaction Surveys specifically evaluated Restore's ease of placement and removal and overall patient satisfaction with performance. The Rate of Positive Response (RPR) was calculated as the percent of responses that were equal to or greater than neutral, i.e.satisfied with that aspect of device function. **Question 2 evaluated the ease of device placement. Ninety percent of patients found the device easy to place at the first study visit and 95% at 3 months. Question 3 evaluated the ease of device removal. One hundred percent of patients found the device easy to remove during the study.** Noting that correct device placement is critical to performance, Question 7 evaluated overall patient satisfaction with Restore. Ninety three percent of patients were satisfied with device performance at the first study visit and 98% at 3 months. **This data confirms that Restore is easy to place and remove and that patients are satisfied with device performance.** Furthermore, patients found the device convenient, able to remain in place during activity, improved their enjoyment of life and self confidence. Finally, patients demonstrated a high degree of satisfaction with device comfort.

A six week Post Device Utilization Period assessed subjects degree of urine loss after device discontinuation. PdWt, PST and IEPD testing demonstrated statistically significant improvement in urine loss during this period compared to the Baseline control. This response, however, deserves further investigation before any long term therapeutic claims can be made.

B. Safety

To provide clinical safety assurance of the Restore Continence device, objective assessment of Safety included 1) urine cultures 2) irritation questionnaire and 3) periodic physical examinations.

Frequent urine cultures revealed a 1.5% prevalence and 3% incidence of positive urine cultures during device usage. Based on literature review of the age-specific prevalence of bacteriuria in incontinent females, this low prevalence rate is significantly below historic figures of 10-38%.

Satisfaction Survey Question 8 quantitates vaginal irritation. The Mean Response and Rate of Positive Response were relatively high throughout the Study signifying that the Restore device was well tolerated in the vast majority of patients.

Adverse events on physical examination were few, minimal, and self limited. No therapeutic intervention was required in any patients and no complications or sequelae occurred.

Analysis of patients Withdrawing from the Study demonstrated that the most common reason cited was inability to keep scheduled visits. Only 5% withdrew because of vaginal irritation. Furthermore, PdWt and PST demonstrated a statistically significant improvement in urine loss in this subgroup during device use which was equivalent to subjects completing the Study.

C. Conclusions

The safety of the Restore device was demonstrated by extensive nonclinical and clinical testing. Technological characteristics do not raise new types of safety and effectiveness questions relative to predicate devices. The Clinical Study demonstrated that the Restore device did not effect the incidence or prevalence of significant bacteriuria. The device was well tolerated by the vast majority of patients. The efficacy of the Restore device was demonstrated by both objective and subjective measures. The clinical data showed that statistically significant improvement was obtained by subjects using Restore. Satisfaction Surveys demonstrated that the device is easy to place and remove with high patient satisfaction with device performance. In summary, these data provide reasonable assurance that the Restore Female Continence Device is a safe and effective alternative for women requiring stress incontinence management and is statistically equivalent to the predicate device.

10. Clinical/Market Experience

Confirming the safety data reported in its clinical study, NEBL has received no significant adverse event reports since the product's release.

Physicians associated with the clinical study and/or with clinical expertise using Restore have attested that patients can adequately self select and use Restore on a non-prescription, over-the-counter basis based on its Instructions For Use. Furthermore, patients have also supported the concept of non-prescription OTC access to the product.

11. Conclusions

The safety and efficacy of Restore has been demonstrated by nonclinical and clinical testing. Comparison with Impress Soft Patch shows that both devices are substantially equivalent in function and indications and that Restore appears to be easier to place and utilize. Clinical experience derived from patients and physicians confirm that Restore can be used over-the-counter based on its product labelings. This data, supports NEBL's claim that Restore is equivalent to its predicate device and therefore should receive non-prescription, over-the-counter market approval.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 5 1999

Jeffrey A. Dann, M.D.
NEBL, Inc.
44 Terrace Drive
Worcester, MA 01609

Re: K983164
Restore (Re/stor) Female Incontinence Device
Dated: December 9, 1998
Received: December 10, 1998
Unclassified/Procode: 78 MNG

Dear Dr. Dann:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K983164

Device Name: NEBL, Inc. Restore Device

Indications For Use:

The Restore device is indicated for the prevention or decrease of episodes of urine leakage in women with stress incontinence.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (21 CFR 801.109) OR Over-The-Counter Use X

(Optional Format 1-2-96)